K013154

OCT 1 9 2001

510(k) Summary

Introduction

This 510(k) Summary document is intended to comply with the requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Submitted by

Dentsleeve Pty Ltd
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Wayville, South Australia
Australia 5034

USA Submission Correspondent

Robert N. Clark
Medical Device Regulatory Advisors
Tel: 303-234-9412 / Fax: 303-234-9413

Date Prepared

September 19, 2001

Trade Name of Device

Mark II / Mark III Manometric Perfusion Pump

Common Name of Device

Manometric Perfusion Pump

Classification Name

System, Gastrointestinal Motility (Electrical)

510(k) Classification

21CFR§876.1725 Class II

Device Description and Intended Use

When used in conjunction with a gastrointestinal manometric assembly (catheter), the Manometric Perfusion Pump can be used where gastrointestinal manometry is indicated when the following conditions are satisfied: 1) When information about patterns of gastrointestinal pressures is judged to be of importance for either determining appropriate patient management or for research studies into gastrointestinal motility. 2) Contraindications are considered, and the risk-benefit analysis is judged to favor performance of the manometric study, after measures have been taken to minimize all possible risks.

Comparison to Predicate Devices

The device is equivalent in safety and performance to prior legally marketed devices. In particular it is equivalent to:

K980946 – Mark II / Mark II CO2 Flush Manometric Perfusion Pump, manufactured by Dentsleeve Pty Ltd.

Recognized Standards

The requirements of the following standards have been used in part to establish substantial equivalence:

IEC 601-1 (1988) Medical Electrical Equipment – Part 1: General Requirements for Safety; including Amendment 1 (1991) & Amendment 2 (1995).

IEC 601-1-2 (1993) Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests

Clinical Testing

The company did not conduct, nor depend on, clinical studies in order to establish substantial equivalence.

Risk Management

This device has been designed to either completely eliminate or mitigate all known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program. One or more of the following means (in order of preference) was used to implement mitigation of health hazards identified by the risk management program:

1. Design modifications.
2. Detection of hazard conditions and alerting of the user.
3. Identification of any potentially undetectable health hazard conditions in the instructions for use or other device labeling.

The user must be qualified in gastrointestinal diagnostic procedures, trained in the use of manometric perfusion pumps and recording equipment; trained in the insertion and use of gastrointestinal manometry catheters; and must be familiar with all labeling and instructions for use associated with the device. The company believes many device health hazards are due to user error and failure to follow instructions for use.

Dentsleeve Pty Ltd believes that the Mark II / Mark III Manometric Perfusion Pump products are safe and effective when used as instructed by knowledgeable and trained personnel, and perform as well as or better than the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2001

Dentsleeve Pty. Ltd.
c/o Mr. Robert N. Clark
Medical Device Regulatory
Advisors
13605 West 7th Avenue
GOLDEN CO 80401-4604

Re: K013154
Trade/Device Name: Mark II / Mark III Manometric Perfusion Pump
Regulation Number: 21 CFR §876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: 78 FFX
Dated: September 17, 2001
Received: September 20, 2001

Dear Mr. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K013154

Device Name: Mark II / Mark III Manometric Perfusion Pump

Indications for Use:

When used in conjunction with a gastrointestinal manometric assembly (catheter), the Manometric Perfusion Pump can be used where gastrointestinal manometry is indicated when the following conditions are satisfied:

1) When information about patterns of gastrointestinal pressures is judged to be of importance for either determining appropriate patient management or for research studies into gastrointestinal motility.

2) Contraindications are considered, and the risk-benefit analysis is judged to favor performance of the manometric study, after measures have been taken to minimize all possible risks.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013154